

REMARKS

Applicant respectfully requests reconsideration. Claims 37, 39-45 and 47-56 were previously pending in this application. No claim is amended or canceled herein. Claims 37, 39-45 and 47-56 are still pending for examination with claims 37, 45 and 54 being independent claims. No new matter has been added.

Double Patenting Rejection

Claims 37, 39-45 and 47-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-31 and 33-39 of U.S. Patent No. 7,576,066. Specifically, the Office asserts that although “although the conflicting claims are not identical, they are not patentably distinct from each other because the application and issued patent claims are directed to a method of administering a antigen (vaccine) and immunostimulatory oligonucleotide adjuvant to a subject” (Office Action page 3).

The instant claims are not properly rejected under the doctrine of obviousness type double patenting over US 7,576,066 because US 7,576,066 and the instant patent application are not commonly owned and do not have identical inventive entities. An obviousness type double patenting rejection is inappropriate in this situation. Obviousness type double patenting relates to common ownership. As stated in MPEP 804IIB1 “Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement.” (emphasis added). An obviousness-type double patenting rejection requires the subject application and cited patent to be commonly owned, rather than to be commonly assigned. According to MPEP 706.02(1) the “term ‘common ownership’ means wholly owned by the same person(s) or organization(s) at the time the invention was made.” The instant patent application is owned by the University of Iowa Research Foundation, Coley Pharmaceutical Group (now owned by Pfizer), and the United States Government as represented by the Secretary, Department of Health and Human Services, and the inventors are Krieg, Klinman, and Steinberg. US 7,576,066 is owned by Coley Pharmaceutical Group (now owned by Pfizer) and the inventor is Krieg. The University of Iowa Research Foundation and the United States Government are not

owners of US 7,576,066. Although the patent application and the patent have one common inventor and no owners in common, the application and patent are not commonly owned (common ownership requires all of the same owners). An obviousness-type double patenting rejection requires the subject application and cited patent to be commonly owned.¹ Thus, it is requested that the rejection be withdrawn.

Even if double patenting were an appropriate rejection in the instant case, the rejection should not stand because a prima facie rejection of obviousness has not been established for all of the pending claims in view of the claims of the issued patent. For instance, claims 40-44 of the instant application include limitations directed to specific nucleic acid delivery complexes, which are not disclosed in the issued patent. Claim 41 adds the limitation that the complex is a cationic lipid, which is not disclosed in the issued patent. Claims 42 and 43 require that the complex is covalently or ionically linked to the ODN, respectively, neither of which is disclosed in the issued patent. Claim 44 requires that the complex is a sterol. None of the recited limitations are included in claims 27-31 and 33-39 of U.S. Patent No. 7,576,066. A prima facie case of obviousness has not been established for pending claims 40-44 in view of claims 27-31 and 33-39 of U.S. Patent No. 7,576,066.

Additionally, claims 45, and 53-56 have specific sequence limitations that are not included in the claims of the cited patent. The claims of claims U.S. Patent No. 7,576,066 are directed to a specific ODN, referred to as SEQ ID NO 1 (tcgtcgtttttcgtgcgtttt). Claim 45 requires that the oligonucleotide comprises 5'-TCAACGTT-3', 5'-TGACGTT-3', or 5'TGACGTC3'. The Office has not presented any evidence that it would have been obvious to use an oligonucleotide having the sequence 5'-TCAACGTT-3', 5'-TGACGTT-3', or 5'TGACGTC3' in view of a disclosure that an oligonucleotide having the sequence tcgtcgtttttcgtgcgtttt is useful. Claim 54 includes the limitation that the oligonucleotide has an unmethylated cytosine-guanine dinucleotide that is flanked by two 5' purines and two 3' pyrimidines. The claims of U.S. Patent No. 7,576,066 do not suggest that an oligonucleotide having unmethylated cytosine-guanine dinucleotide that is flanked by two 5' purines and two 3' pyrimidines should be used. Therefore, the Office has not established a prima facie rejection of claims 45, and 53-56 of the pending application.

¹ See MPEP §804; *Longi*, 759 F.2d at 895, 225 USPQ at 650.

Accordingly, withdrawal of the rejection of claims 37, 39-45 and 47-56 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70083US05.

Dated: March 4, 2011

Respectfully submitted,

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